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| 10/079,468  | 02/19/2002  | Christopher M. Fender | 399483                      | 6678             |
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|   |             |                       | ART UNIT<br>1631            | PAPER NUMBER     |

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Please find below and/or attached an Office communication concerning this application or proceeding.



## **DETAILED ACTION**

### ***CLAIMS UNDER EXAMINATION***

Applicant's argument, filed 12/16/2005, are persuasive regarding previous rejections, however, upon reconsideration new issues have been found and are summarized below. Claims herein under examination are claims 1-4, 8-13, and 20. Claims 5-7 have been cancelled. Claims 1, 12, and 20 are currently amended. Claims 14-19 and 21-34 are again withdrawn without traverse.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **CLAIM REJECTIONS - 35 USC §112, 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method wherein separate spectra for resistant and susceptible plants are obtained and compared [0064], does not reasonably provide enablement for a method wherein mixtures of spectra for both resistant and susceptible plants are obtained and compared. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below which leads to the determination that the above claim lacks enablement due to undue experimentation being required to make and use the invention.

In the instant case, the claimed subject matter, drawn to a method for predicting the soybean cyst nematode resistance of a soybean sample, lacks enablement for the following reasons:

- The method of Claim 1, drawn to steps (a)-(c), results in predicting the soybean cyst nematode resistance based upon "comparison results" using discriminant analysis. However, while the specification does provide examples of obtaining separate spectral data and discriminant analysis of separate spectral data [0050],[0064],[0065], these examples do not provide sufficient guidance as to use a predictive model based on corresponding spectral data obtained from a mixture (i.e. combination) of both resistant and susceptible genotypes, as recited in instant claim 1(b). [Wands factors (2), (3)].
- Methods of discriminant analysis, which are well known in the art, are typically used to determine between multiple naturally occurring groups containing distinct data sets (<http://www.statsoft.com/textbook/stdiscan.html>). However, prior art does not teach

discriminant analysis for groups that contain mixtures of data (e.g. NIR spectral data). Thus, given the steps of the instant invention drawn to a spectral group containing a mixture of spectral data from SCN resistant plants and SCN susceptible plants, one of ordinary skill in the art would require undue experimentation to predictably practice the instantly claimed invention. [Wands factors (1), (2), (6), (7)].

### **CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 8, 9, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "based upon" in steps (b) and (c). It is unclear whether the discriminant model is based upon a predictive model or regression analysis. Clarification is requested. Claims 2-4, and 8-11 are rejected as they depend from claim 1.

Claim 4 recites the limitation "visual comparison between the assay spectra and the predictive model." As written, it is unclear whether spectra or models are being compared. Clarification is requested.

Claims 8 recites a "natural intelligent algorithm." It is unclear in what way an algorithm can be considered "natural." Clarification is requested. Claim 9 is rejected as it depends from Claim 8.

Claim 8 recites the limitation "the model". There is insufficient antecedent basis for this limitation. This rejection may be overcome by inserting ---predictive--- before "model" in line 1.

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Claim 20 recites a "machine readable form" in the preamble. It is unclear whether a machine readable form is a physical form, code, or otherwise. Clarification is requested.

### **Claim Rejections - 35 USC § 103**

Applicant's arguments with respect to claim 1-4, 10-13, and 20 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 10-13, and 20 are rejected under 35 U.S.C. 103(a) as being obvious by Qui et al. (Biotechnology And Bioengineering, Vol. 44, No. 1, 1994), in view of Malins et al. (US Pat. No. 6,214,550; Filed: June 25, 1998).

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Qui et al. teach a method for determining soybean cyst nematode resistance (SCN) comprising the use of NIR spectroscopy, as discussed in the previous office action mailed 6/17/2005.

Qui et al. do not specifically teach "regression analysis comparing peak intensity...between the assay and corresponding spectra" (incorporated into Claims 1 and 12 by amendment).

Malins et al. teach methods for screening for a tumor based on characterization of DNA by spectral analysis (Abstract). More specifically, Malins et al. teach the following:

- Obtaining and analyzing IR spectral data to obtain principal component (PC) scores [Background of the Invention (17)].
- Comparing peak intensities of spectral data with a predictive model that is based upon regression analysis and PC scores (i.e. spectral data) [Detailed Description of the Invention (24)]
- Comparison of assay and corresponding spectra over predetermined IR frequency ranges [Figs. 2A-1, 2A-2, 3A, and 9].

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the invention of Qui et al. with the multivariate spectral discriminant analysis model of Malins et al., where the motivation would have been to discriminate between alterations in DNA based on IR spectral analysis [Malins et al., Applications of FT-IR Technology (55)]. One skilled in the art would reasonably have expected success in combining Qui et al. and Malins et al. because both teach discriminant analysis of IR spectral data.

Claims 1-4, 8-13, and 20 are rejected under 35 U.S.C. 103(a) as being obvious by Qui et al. (Biotechnology And Bioengineering, Vol. 44, No. 1, 1994), in view of Borggaard et al. (Anal. Chem. 1992, 64:545-551).

Qui et al. teach a method for determining soybean cyst nematode resistance (SCN) comprising the use of NIR spectroscopy, as discussed in the previous office action mailed 6/17/2005.

Qui et al. do not specifically teach a "natural" intelligent algorithm (as in instant claims 8 and 9).

Borggaard et al. teach a method of optimally interpreting NIR spectra using a neural network for classifying samples or calibrating instruments for quantitative determination (Abstract and p. 546, Section I). Ethanol and latex NIR spectra [p. 547, Section V], as well as ground pork samples [p.548, col. 1, lines 9-14] are used in experimentation.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the invention of Qui et al. with the neural network model of Borggaard et al., where the motivation would have been to use an efficient method for classification of noisy or non-linear (i.e. biological) NIR spectra for quantitative determination [Borggaard et al., p.550, Section VIII]. One skilled in the art would reasonably have expected success in combining Qui et al. and Borggaard et al. because both teach spectral analysis of NIR data.

### **CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 5:30pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
2/16/06